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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/533,826	04/06/2006	Gerard Marx	2488.014	8215
23405 7590 09/21/2007 HESLIN ROTHENBERG FARLEY & MESITI PC 5 COLUMBIA CIRCLE ALBANY, NY 12203				
			EXAMINER AUDET, MAURY A	
			ART UNIT 1654	PAPER NUMBER
			MAIL DATE 09/21/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

**Office Action Summary**

Application No.

10/533,826

Applicant(s)

MARX ET AL.

Examiner

Maury Audet

Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 7/10/07.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) \_\_\_\_\_ is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☒ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>5/2/06</u>  | 6) <input type="checkbox"/> Other: _____                          |

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### DETAILED ACTION

The present application has been transferred from former Examiner Young to the present Examiner.

#### *Election/Restrictions*

Applicant's election without traverse of Group I, claims 1-10 and 34-36, as drawn to the elected peptide of the invention, a peptide consisting of SEQ ID NO: 1 in the reply filed on ~~08/07~~ 7/10/07 is acknowledged. Claims 11-33 and 37-43 are withdrawn from consideration. Claims 1-10 and 34-36 have only been examined in so far as they read upon the elected peptide of the invention, a peptide consisting of SEQ ID NO: 1.

#### *Claim Rejections - 35 USC § 112 2nd*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-10 and 34-36 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In e.g. claim 1, it is unclear what is meant by the phrase "the peptide is characterized in that it elicits cell attachment responses"? Namely, attachment to what? How does the peptide elicit this, by attachment to a cell, chemical signals via another receptor to said cell? And what type of responses by said cell are contemplated? The invention has not been distinctly claimed.

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It is suggested that Applicant adopt the identical claim language as that of Applicant's earlier application to related haptotactic peptide, namely claim 1 of issued U.S. Patent 7,148,190, as regards present independent claims 1, 34 and 36:

An isolated haptotactic-peptide liposomal composition/pharmaceutical composition/cosmetic composition [of 20 amino acids] comprising a peptide consisting of the amino acid sequence as set forth in SEQ ID NO:1, characterized in that the haptotactic peptide induces cell attachment to a surface to which the haptotactic peptide is covalently bound, inasmuch as the number of cells attached to the surface is at least 50% greater than the number of cells attached to the surface in the absence of the peptide.

The other limitations of claims 34 and 36 would have to be added, respectively, as well. It is noted that SEQ ID NO: 1 in the above issued patent is a distinct peptide from that of the presently elected SEQ ID NO: 1 of this application.

In e.g. claim 36, it is unclear what is meant by "cosmetic beneficial effect"? It is understandable that these compositions convey some pharmaceutical benefit, assuming cell attachment functionality is possible, as acknowledged in issued in U.S. Patent 7,148,190. However, a clear description as to specifically a "cosmetic beneficial effect" or cosmetic composition, based on the peptide was not found. If is the liposome properties, and not the peptide, that somehow carries this out, such should be distinctly claimed.

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### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-10 and 34-36 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4 of U.S. Patent No. 7,122,620 (09/847,790). Although the conflicting claims are not identical, they are not patentably distinct from each other because the '620 patent is drawn to a peptide or any type of composition comprising identical SEQ ID NO: 1. Although the present application is to a "liposomal" compositions comprising SEQ ID NO: 1, compositions comprising liposomes need no reference for an introduction. The use of liposomes to carry e.g. other active agents, in combination with peptides has been well known in the art for over a decade a routinely used form of compositions. Absent evidence to the contrary the these specific liposomes carry some other unexpected property not routinely used within the peptide composition arts.

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Claims 1-10 and 34-36 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 11-20 of copending Application No. US 20070009571 (11/490,033). Although the conflicting claims are not identical, they are not patentably distinct from each other because the '571 claims 11-20 are drawn to compositions/products comprising SEQ ID NO: 1, identical to presently elected SEQ ID NO: 1, and elected products thereof. Although the present application is to a "liposomal" compositions comprising SEQ ID NO: 1, compositions comprising liposomes need no reference for an introduction. The use of liposomes to carry e.g. other active agents, in combination with peptides has been well known in the art for over a decade a routinely used form of compositions. Absent evidence to the contrary the these specific liposomes carry some other unexpected property not routinely used within the peptide composition arts..

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-10 and 34-36 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2 of copending Application No. 11/601,024 (US 20070066535). Although the conflicting claims are not identical, they are not patentably distinct from each other because the '024 claims 1-2 are drawn to a peptide/product comprising a peptide of at least 50-70% identity to the carboxy termini of fibrinogen. Read in light of the specification, SEQ ID NO: 14 meets the limitations of 1-2 of '024 and SEQ ID NO: 14 is identical to presently elected SEQ ID NO: 1, and elected products thereof. Although the present application is to a "liposomal" compositions comprising SEQ ID

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NO: 1, compositions comprising liposomes need no reference for an introduction. The use of liposomes to carry e.g. other active agents, in combination with peptides has been well known in the art for over a decade a routinely used form of compositions. Absent evidence to the contrary the these specific liposomes carry some other unexpected property not routinely used within the peptide composition arts.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### ***Claim Objections***

Claims 1-10 and 34-36 are objected to because of the following informalities: is the protect lexicography desired "haptotactic-peptide liposomal" or "Haptotactic Peptide-Liposomal" See claim 1 versus claim 34/36.

Appropriate correction is required.

### ***Citation of Pertinent Art Not Relied Upon***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Regarding the subject matter of haptotactic peptides, Applicant has one other issued patent, related, though drawn to distinct haptotactic peptides (all under examination by Examiners other than the present):

US 7,148,190 (10/181,187)

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maury Audet whose telephone number is 571-272-0960. The examiner can normally be reached on M-Th. 7AM-5:30PM (10 Hrs.).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MA, 9/14/2007

A handwritten signature in black ink, appearing to read 'Maury Audet', with a long horizontal flourish extending to the right.

MAURY AUDET  
PATENT EXAMINER